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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,505	11/28/2001	Raymond J. Wong	3192-002	2941
33432	7590	08/20/2004	EXAMINER	
KILYK & BOWERSOX, P.L.L.C. 53 A EAST LEE STREET WARRENTON, VA 20186			MENON, KRISHNAN S	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 08/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/996,505	<b>Applicant(s)</b> WONG, RAYMOND J.	
	<b>Examiner</b> Krishnan S Menon	<b>Art Unit</b> 1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11, 13-38 and 50-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-38 and 50-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-11, 13-38, and 50-61 are pending.

In view of the appeal brief filed on 7/2/04, PROSECUTION IS HEREBY REOPENED.

New ground for rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1, 3-9,11,13-16,19-25,29-38,and 50-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's own disclosure of prior art (REDY™) in view of Polak et al (US4,650,587).

Applicant's disclosure of prior art REDY™ teaches a sorbent cartridge having several layers of sorbents such as zirconium phosphate (ZrP), zirconium hydrous oxide (HZO), activated carbon, etc., (specification pages 5-8 and figure 1 and 8), but does not teach sodium zirconium carbonate as one of the layers as in claims 1 and 11. Polak teaches a sorbent capsule comprising sodium zirconium carbonate (see col 5 line 68 – col 6 line 11) as phosphate ion absorber and/or for enteric elimination of urea. It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Polak in the teaching of REDY™ for sorption of urea and phosphate ions because SZC is the state of the art for phosphate ion absorption and/or because of the problems associated with ZrP used by REDY as taught by Polak (see Polak col 3 lines 11-36 and col 6 lines 1-2).

Claims 3 and 13 add the further limitation of ZrP/group IVB metal phosphate, and claims 4 and 13 have ZrP as a layer as taught by REDY.

Claim 5 adds the molecular composition of ZrP, and claim 6 adds the characteristics of ZrP (material property), taught by REDY.

Claims 7 and 8 add limits on residual sulfate and chloride in ZrP (material property). Claim 9, pH of ZrP is a material property.

Claim 14 adds alumina, alumina supported urease, granular activated carbon, or combination thereof, with claim 15 adding these in layers (taught by REDY).

Claim 16 adds the order of the layers as taught by REDY except for the position of the granular activated carbon layer (applicants admit that it could be in any order on page 21 lines 22-23). *An applicant's expressed recognition of an art-recognized or*

*obvious equivalent may be used to refute an argument that such equivalency does not exist:* In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958). Applicants have not shown, with evidence, any particular, non-obvious, advantage of changing the position of activated carbon.

Claim 19: The composition of sodium zirconium carbonate by empirical formula is given in col 6 lines 1-9 of Polak, except for the LOD of 30-40%, which is due to water loss. However, water loss from drying sodium zirconium carbonate is an inherent material property. If the composition as claimed by the applicant is different, that needs to be clearly shown.

Claims 20 and 21: Polak does not specify if the sodium zirconium carbonate satisfies the ANSI/AAMI standard, and the properties listed. However, it would be obvious to one of ordinary skill in the art at the time of invention that the material being the same, it would satisfy such a requirement. Inherency: Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

Claims 22 adds ZrO and Claim 23 has ZrO in acetate form (taught by REDY).

Claims 29- 31: the quantity of the sodium zirconium carbonate, ZrP, and other components in instant claims is a design/optimization issue depending on the required capacity of the cartridge and the composition of the solution to be treated. Discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art. In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980); In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); In re Aller, 42 CCPA 824, 220 F.2d 454, 105 USPQ 233 (1955).

Claim 32 and 36 add immobilized enzyme (Urease in alumina), ion exchange materials (sodium zirconium phosphate), and adsorbent for creatinine (activated carbon), etc, all taught by REDY.

Claim 33 and 37 add chlorine removal material (activated carbon), Claims 34 and 35 add materials in layer form (see fig 1, REDY).

Claim 38 has the added limitation of two or more layers of the absorbents in the cartridge. REDY™ teaches several layers.

Claim 50: Polak in view of REDY™ also teaches an apparatus for conducting dialysis wherein the sorbent cartridge is in fluid communication with a dialyzer.

Claim 51: the dialysis fluid could be spent hemo-dialysis fluid (Polak – abstract)

Claims 52, 54 and 57: The spent fluid could be restored to the original Na<sup>+</sup> and HCO<sub>3</sub><sup>-</sup> content (abstract of Polak, and REDY™)

Claim 53: The apparatus could be in blood communication with a patient (see REDY™)

Claim 55 and 56: peritoneal dialysis (See Polak fig, col 5 lines 60-68, and the fig, col 2 lines 25-40 and claim 8 of the incorporated ref).

Claims 58 and 59 add the functional limitation of restoring the levels of sodium and bicarbonate in the dialysate to the fresh dialysate levels [functional limitation: While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also In re Swinehart, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); In re Danly, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims

cover what a device is, not what a device does.” Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).]

Re claims 24 and 25, claim 24 has ratio of ZRO/sodium zirconium carbonate as 1:1 and claim 25 has them blended together. REDY teaches ZrO for removal of phosphate and heavy metals (fig 8 of spec), sodium zirconium carbonate is for the removal of phosphates (Polak). It would be obvious to one of ordinary skill in the art at the time of invention that these two would be put together, since they are for similar functions and one would blend them together, since Polak does not teach any specific the structure of the carbonate in the cartridge. Determining the ratio of the two would be only an optimization based on the capacity needed and the contamination in the solution to be treated [In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980); In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); In re Aller, 42 CCPA 824, 220 F.2d 454, 105 USPQ 233 (1955).].

Re claims 60 and 61, the location of the SZC layer is further away from the ZrP layer, which is taught by REDY™ (see fig 1 of spec), since it is already established that the SZC layer is equivalent to the HZO-Ac layer of REDY™.

2. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's own disclosure of prior art (REDY™) in view of Polak et al (US4,650,587) as in claim 1 above and further in view of Smakman, et al (US 4,542,015).

Claim 2 adds the limitation, 'one of said layers consisting essentially of sodium zirconium carbonate', REDY™ teaches use of "HZO-Ac" as a separate layer for PO4



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absorption (specification page 5). Polak teaches SZC as 'the state of the art' PO4 absorber. It would be obvious to one of ordinary skill in the art at the time of invention to the teaching of Polak in the REDY™ cartridge for PO4 absorption because, Polak teaches that SZC is the state of the art for phosphate ion absorption, and because of the problems associated with HZO as taught by Smakman et al (toxic side-effect, reproducibility, rapid deterioration – see col 2 lines 31-37). Also, SZC and HZO-Ac are equivalent and performs the identical function specified in the claim (as taught by Polak) in substantially the same way, and produces substantially the same results as the corresponding element disclosed in the specification. *Kemco Sales, Inc. v. Control Papers Co.*, 208 F.3d 1352, 54 USPQ2d 1308 (Fed. Cir. 2000)

3. Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's own disclosure of prior art (REDY™) in view of Polak et al (US4,650,587) as in claim 1 above and further in view of Potts (US 5,234,603).

Claims 26-28 adds the further limitations of basic zirconium carbonate, its composition, and purity, respectively, which REDY in view of Polak does not teach. Potts teaches the basic zirconium carbonate (pH 9-14) for removal of heavy metals, transition metals and organic matter from wastewater (col 3 lines 55-61, col 4 lines 19-43), and that zirconium carbonate would hydrolyze to form the polymeric oxide chain (see structure at line 35, col 4 of Potts). It would be obvious to one of ordinary skill in the art at the time of invention to have the teaching of Potts in the teaching of REDY™

in view of Polak for the removal of heavy metal and transition metal ions from the dialysate as taught by Potts.

4. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's own disclosure of prior art (REDY™) in view of Polak et al (US4,650,587) as applied to claim 16 above, and further in view of Marantz et al (US 3,669,880).

Claims 17 and 18 add structural components like filter pads and diffuser. REDY teaches a filter pad (fig 1), but not the diffuser for flow distribution. Marantz teaches a flow distributor and filter pads (see figures 2,3). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Marantz in the teaching of REDY in view of Polak for the flow distribution and for preventing the breaking up and inter-mixing of particles in layers as taught by Marantz (col 2 lines 10-30).

5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's own disclosure of prior art (REDY™) in view of Polak et al (US4,650,587) as applied to claim 3 above, and further in view of Tawil et al (US 4,025,608).

Claim 3 adds the further limitation of particle size to 30-40 microns for the ZRP particles, which REDY in view of Polak does not teach. Tawil teaches the particle size of ZRP (col 2 lines 54-59). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Tawil in the teaching of REDY in view of Polak for the particle size of ZrO for good flow distribution as taught by Tawil.

### ***Response to Arguments***

Applicant's arguments filed with the appeal brief on 7/2/04 have been fully considered but they are moot because of the new grounds for rejection.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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